Field Safety Notice RA2017-011

April 21th 2017

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2017-011

Type of Action: Field Safety Corrective Action: **Return to supplier.**

Description: Exeter Stem size 0.

Catalog #: 0580-1-440

Lot #: G6106543

Dear Distributor/ Risk Management/Surgeon:

On April 11, 2017 Stryker® Orthopaedics ("Stryker") initiated a voluntary, lot-specific recall for the Exeter Stem size 0 referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the instrument covered by this Safety Notice and list the risk mitigation factors.

Issue:

Stryker has received customer inquiries stating that there was no laser etchings on Exeter stem ref 0580-1-440 Lot G6106543.

Potential Hazards:

The potential risks associated with these events are listed below.

(1) No markings on the device.

(2) Insufficient cement mantle in the proximal-medial region.

(3) Excessive cement mantle in the proximal-medial region.

The aforementioned potential hazards may result in the following patient harm:

Implant loosening due to improper seating of implant.

Risk Mitigation

With the product markings missing, the surgical staff should reference the product labels to acquire the required information to identify the device. All critical information is available on the product labels.

As all markings are missing from the device, and not just the depth markers, awareness of the non-conformance is heightened. Identification of the missing markings by surgical staff prior to

the femur being cemented may lead to surgical staff rejecting the Exeter stem and retrieving a replacement conforming device.

Surgeon experience with the Exeter femoral system; users with experience of the Exeter femoral system may be familiar enough with the shape and contours of the stem to know what the implant should look like when correctly seated.

Our records indicate that you have received the above referenced instrument. Please assist us in meeting our regulatory obligation by:

1. Immediately check your internal inventory and quarantine all subject devices.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
5. Complete the attached customer response form and return the form and any affected devices to your local Stryker Representative.
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)
6. Please inform Stryker of any adverse events associated with the use of the subject devices.
   a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

Stryker maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours Sincerely,

Sara Jato
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STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

April 21, 2017

SURGEON

ADDRESS

CITY, STATE ZIP

FSCA identifier: Product Field Action **RA2017-011**

Description Exeter Stem size 0.

Catalog #: 0580-1-440

Lot Code: G6106543

Type of Action: **Return to Supplier**

I have received the notification from Stryker® Orthopaedics dated April 21 2017 stating that they initiated a Field Safety Corrective Action of the above referenced implant.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)